

**KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT
IMMUNIZATION PROGRAM
Protocol for the Prevention of Perinatal Hepatitis B
September 2001**

A. Prenatal Hepatitis B Screening Procedure

All pregnant women who receive prenatal care at a local health department or private physician are to receive:

1. An assessment of her risk for contracting hepatitis B disease;
2. Information on how she can reduce her risk of infection with hepatitis B;
3. An explanation of why she is being tested for hepatitis B;
4. *A serological screen for hepatitis B surface antigen as per amended KS-153f*
(see attachment 1)

NOTE: Physicians may choose to have the hepatitis B screening done by the Kansas Department of Health and Environment (KDHE) laboratory free of charge. The specimen must be sent through the Local Health Department (LHD).

B. Description of Serological Screening

1. Collect approximately 7ml of whole blood in a "red top" tube (no additives) from each woman. The sample should **NOT** be spun down and must be refrigerated until it is sent to the KDHE laboratory.

NOTE: For the Maternal and Infant (M&I) Program, approximately 10 ml of blood is in order to test the sample for syphilis and rubella.

2. Send the blood **UNREFRIGERATED**, ideally the same day as collection, but no later than seven days after collection to:

**KDHE Laboratory
Forbes Field, Bldg. 740
Topeka, KS 66620**

A single hepatitis mailer or multi-mailer may be used to send specimens to the laboratory. Mailers may be obtained from the laboratory by calling (785)296-1653.

The KDHE Laboratory will report the test results (positive or negative) to the Local Health Department. Positive test results will go to both the Local Health Department and the Hepatitis B Coordinator with the Kansas Immunization program.

- NOTE:**
1. If a multi-mailer is used, complete and submit a hepatitis lab slip for each sample to be tested for HBsAg.
 2. Mark "PRENATAL" in the section labeled "Purpose of Test".
 3. If the mother is an M&I client, mark "Prenatal and M&I" in the section labeled "Purpose of Test".
 4. Include the appropriate lab slip for other serologic tests required.
 5. A private physician, not employed under the auspices of a Local Health Department **may not** submit specimens for HBsAg testing directly to the KDHE laboratory.

C. Follow-up of Test Results

1. *Negative* test results

The health care provider should inform each woman who has tested negative for HBsAg and review risk reduction with the client.

NOTE: Women who are negative for HBsAg during their initial screening and who are suspected of having acute hepatitis B, or who have a particularly high risk behavior, (i.e. intravenous drug abuse) are to have a repeat HBsAg test drawn between the 34th and 36th week of pregnancy. This repeat test may be done by the health department or by a private physician. If the woman is found to be positive through the rescreen, the household and sexual contacts should be followed in the same manner as a woman who tests positive during the initial screen.

2. *Positive* Test Results

The health care provider will:

- a. Counsel a woman who has tested positive for HBsAg and provide her with information on health care.
- b. Counsel the woman regarding risk reduction for protection of her household and sexual contacts.

NOTE: Notify the woman's private health care provider only if she consents to the release of the information.

- c. Provide a hepatitis B carrier card to all HBsAg positive women. Instruct her to present the card to hospital staff at the time of delivery. (hepatitis B carrier cards are available from the Kansas Immunization Program to private providers upon request.)

- d. Notify the appropriate hospital that the infant born to a HBsAg positive woman will need to be vaccinated with HBIG and hepatitis B vaccine within 12 hours of birth (preferably the delivery room). Refer to Table 1 for recommended schedule and Table 2 for recommended dosage.

TABLE 1

Recommended schedule of hepatitis B immunoprophylaxis to prevent perinatal transmission of hepatitis B virus infection

Infant born to mother known to be HBsAg* positive:		Infant born to mother not screened for HBsAg*:	
Vaccine Dose:	Age of Infant:	Vaccine Dose:	Age of Infant:
First	Birth(w/in 12 hrs)	First	Birth(w/in 12hrs)
HBIG++	Birth(w/in 12hrs)	HBIG++	Birth(w/in 12hrs)
Second	1-2 months	Second	1-2 months
Third	6 months	Third	6 months

* Hepatitis B surface antigen

++ Hepatitis B immune globulin--0.5ml administered intramuscularly at a site different from that used for vaccine.

TABLE 2

RECOMMENDED DOSES OF CURRENTLY LICENSED HEPATITIS B VACCINES

Kansas Immunization Program

Revised October 1999

Merck, Sharpe & Dohme Product				SmithKline Beecham Product		
PATIENT AGE AND STATUS	€ RECOMBIVAX PEDIATRIC FORMULATION (Brown Cap) 5mcg/0.5ml	€ RECOMBIVAX HIGH RISK INFANT/ ADOLESCENT FORMULATION (Yellow Cap) 5mcg/0.5ml	† COMVAX PEDIATRIC FORMULATION (Aqua Cap) Hib Vaccine & Hep B Vaccine Combination 7.5mcg & 5mcg/0.5ml	€™ RECOMBIVAX ADULT FORMULATION (Green Cap) 10mcg/1.0ml	† ENGERIX PEDIATRIC FORMULATION (Blue Cap) 10mcg/0.5ml	†™ ENGERIX ADULT FORMULATION (Orange Cap) 20mcg/1.0ml
Ø Infant born to HBsAg POSITIVE woman	5ug/0.5ml (HBIG given simultaneously at a different site within 12hrs of birth)	5ug/0.5ml (HBIG given simultaneously at a different site within 12hrs of birth)		5mcg/0.5ml (HBIG given simultaneously at a different site within 12hrs of birth)	10ug/0.5ml (HBIG given simultaneously at a different site within 12hrs of birth)	
Ù Infant born to HBsAg NEGATIVE woman	5ug/0.5ml	5ug/0.25ml	Û 5mcg/0.5ml	2.5ug/0.25ml	10ug/0.5ml	
1-10 Years of Age	5ug/0.5ml	5ug/0.25ml		2.5ug/0.25ml	10ug/0.5ml	
11-19 Years of Age	5ug/1.0ml	5ug/0.5ml		5ug/0.5ml	10ug/0.5ml	20ug/1.0ml
Adult ≥ 20 Years of Age		10ug/1.0ml		10ug/1.0ml		20ug/1.0ml

€ If the suggested formulation is not available, the appropriate dose can be achieved from another formulation, provided the total volume of vaccine does not exceed 1.0ml. (From package insert)

† Product licensed for use only as indicated on label.

†™ The Kansas Immunization Program supplies adult vaccine for perinatal HBsAg contacts only.

Note: *COMVAX is not licensed for infants born to HbsAg Positive women.*

↑ Infants born to HBsAg POSITIVE Women		↓ Infants born to HBsAg NEGATIVE Women	
		<u>Option 1</u>	<u>Option 2</u>
Dose 1	Hepatitis B & HBIG given within 12 hrs. of birth	Dose 1 Birth	Dose 1 2 months of age
Dose 2	Hepatitis B given at 1-2 months of age	Dose 2 1-2 months of age	Dose 2 4 months of age
Dose 3	Hepatitis B given at 6 months of age	Dose 3 6-18 months of age	Dose 3 6-18 months of age

Note: *The minimum interval between dose 1 and 2 is one month. The minimum interval between dose 2 and 3 is two months. Infants SHOULD NOT receive their third dose of hepatitis B vaccine prior to 6 months of age, especially those infants born to HBsAg positive women. If there is a long period of time between any dose of hepatitis B vaccine, DO NOT RESTART THE SERIES.*

e.

Pre-vaccination Testing

- Is not recommended for routine vaccination
- Is recommended for household/sexual contacts of HBsAg positive women
- If pre-vaccination testing is indicated, test for anti-HBc

Post-vaccination Testing

- Is recommended for infants born to HBsAg positive women
- Test infants 3 to 9 months after completing the series

NOTE: Each woman should sign a Release of Information Form. However, you may notify the hospital of the woman's test results even if you do not have a signed release form.

- f. The Kansas Immunization program will provide hepatitis B vaccine to hospitals for vaccination of an infant born to an HBsAg positive woman. The vaccine will be sent from the State Program to the Local Health Department. The Local Health Department will then arrange delivery of the vaccine to the hospital.

The Local Health Department will determine the method by which they are notified of the birth and vaccination of the child.

The designated Local Health Department employee shall complete a Perinatal Hepatitis B Surface Antigen Positive Case Report and submit the report to the following address:

Jennifer Hill
Attention: Hepatitis B Coordinator
1000 SW Jackson Street, Suite 210
Topeka, KS 66612-1274

- g. The designated health department employee will arrange to have the woman's household members, needle-sharing partners, and sexual partners tested for anti-HBc. Contacts should be tested for anti-HBc and vaccinated with the first dose of the hepatitis B series on the same day. KDHE will pay for the cost of running the test and supplying vaccine to all household and sexual contacts of a perinatal case of hepatitis B. If the individual is positive for anti-HBc, do not complete the vaccination series. If the contact is negative, complete the hepatitis B vaccine series. Those contacts who test positive for anti-HBc should be evaluated by their healthcare provider to determine if they have acute infection or are a carrier for the disease.

NOTE: Collect 7ml of blood from each contact and follow the instructions in Section B "Serological Screening by the Health Department". Arrange for follow-up doses of hepatitis B vaccine for infants born to HBsAg positive women.

NOTE: If an infant is not vaccinated in the hospital, the designated health department employee must arrange for the infant to receive HBIG and hepatitis B vaccine as soon as possible, WITHIN SEVEN DAYS after birth.

- h. The designated health department employee shall submit a Monthly Hepatitis B Surface Antigen Activity Report to the Kansas Immunization Program which will document results of serological tests, hepatitis B vaccinations and HBIG administration given that month to infants and household/sexual contacts. **A MONTHLY REPORT IS TO BE SUBMITTED TO THE KANSAS IMMUNIZATION PROGRAM EVEN IF NO ACTIVITY HAS OCCURRED.** The report is due by the 10th of each month.

TABLE 3

**GUIDE TO POSTEXPOSURE IMMUNOPROPHYLAXIS FOR
EXPOSURE TO HBsAg POSITIVE WOMEN**

TYPE OF EXPOSURE	IMMUNOPROPHYLAXIS
Perinatal	Vaccination + HBIG
Sexual contact-acute infection	HBIG** ± Vaccination
Sexual contact-chronic carrier	Vaccination
Household contact-chronic carrier	Vaccination

***HBIG to be given within fourteen days of last sexual contact.*

Adapted from CDC, MMWR, Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination, 1991, Volume 40, (No.RR-13) page 6.

References

Centers for Disease Control and Prevention (CDC). Protection Against Viral Hepatitis: Recommendations of the Immunization Practices Advisory Committee (ACIP). Morbidity and Mortality Weekly Report (MMWR), February 9, 1990, Volume 39, pages 1-26.

CDC. Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination. Recommendations of the ACIP. MMWR, November 22, 1991, Volume 40, pages 1-25.

CDC. Prevention of Perinatal Hepatitis B Through Enhanced Case Management-Connecticut, 1994-95, and United States, 1994. MMWR, July 12, 1996, Volume 45, pages 584-587.

D. Tracking Hepatitis B Perinatal Cases and Household Contacts (10/00)

1. Upon receipt of a hepatitis B-positive report on a woman from a laboratory, physician, or someone else from KDHE, please conduct the usual follow-up and determine if the woman is pregnant. If she is pregnant, complete the Perinatal Hepatitis B Surface Antigen Case Report (front and back) and either fax or mail this report to the Hepatitis B Coordinator. By sending this report, it reflects that you are aware of this case and that you have initiated follow-up on the hepatitis B-positive pregnant woman.

Date initiated
Mother's last name
Mother's first name
Mother's date of birth
Mother's race
Mother's HBsAg test date
Expected delivery date
Date initiated for contacts
Contact's name
Contact's relationship to mother
Contact's date of birth
Contact's screen date
Contact's Anti-HBc test result
Contact's Hepatitis B vaccine dates (if needed)
Infant's name
Infant's date of birth
Date of HBIG to infant
Infant's Hepatitis B vaccine dates
Infant's screen date
Infant's HBsAG and Anti-HBs test results
Infant's revaccination dates (if needed)
Mark if infant was NOT born in Kansas

2. Refer to your Immunization Manual under the section "Kansas Immunization Program Perinatal Hepatitis B Prevention Protocols" for specific procedures, including collecting and sending serum for testing to the KDHE laboratory, follow-up of test results, and the recommended schedule of hepatitis B immunoprophylaxis for infants and household contacts. **REMINDER: Infants should be tested for response to the vaccine 3 to 9 months after completing the series, making sure that the child is at least one year of age.**
3. Please fax or mail any updated information by the 10th of each month using either a revised version of the perinatal case report or the printout that is sent on that particular individual. A monthly report should be submitted even if no activity has occurred.

4. Upon receipt of your case report, the information will be entered into the database created to track hepatitis B-positive pregnant women or mother-infant pairs as well as household contacts. Printouts of this information will be sent to you on a quarterly basis. When the database on household contacts is completed, this information will also be sent to you.

NOTE:

- Before determining that the infants or household contacts are lost-to-follow-up, please exhaust all possible means of finding them, as mentioned in the attachment provided.
- If it is determined that the child has moved, find out their new location and inform the state health department of their new residence so that they can continue appropriate follow-up. Please mark that the state health department has been contacted.

Mailing and fax information:

KDHE - Epidemiologic Services
Attn: Jennifer M Hill
1000 SW Jackson, Suite 210
Topeka, KS 66612-1274

Phone number: 785/296-8156
Fax number: 785/291-3775

PERINATAL HEPATITIS B MONTHLY REPORT

TO: Jennifer M Hill

FROM: _____

DATE: ____/____/____

There are no Perinatal Hepatitis B Case Report Updates in _____ county
for

the month of _____.

Please fax or return by the 10th of each month.

KDHE - Epidemiologic Services
Attn: Jennifer M Hill
1000 SW Jackson, Suite 210
Topeka, KS 66612-1274

Phone number: 785/296-8156
Fax number: 785/291-3775

E. Things To Remember

1. If a physician refers an HBsAg positive woman to the Local Health Department for follow-up, obtain a copy of the laboratory report to verify the HBsAg status, and follow the procedure for an M&I client.
 2. The Advisory Committee on Immunization Practices (ACIP) recommends that infants born to HBsAg positive women need to be tested 3-9 months for HBsAg and anti-HBs after the third dose of vaccine to monitor the success or failure of vaccination and HBIG therapy. The KDHE Laboratory can process the test. The Kansas Immunization Program will pay the cost of running these tests if performed at the Kansas Health and Environmental Laboratory.
 - a. If HBsAg is **NOT** detectable, and anti-HBs is present, the child should be considered protected.
 - b. If HBsAg and anti-HBs are **NOT** detected, *the child is considered susceptible*. The child must receive three additional doses of hepatitis B vaccine and be retested one to six months after completing the second series, following the schedule outlined in Table 1. If the child is negative after the second retest, the child should be considered a non-responder. The child is not to receive more than a total of six injections of hepatitis B vaccine.
- NOTE:** All costs for post vaccination testing second re-vaccination with hepatitis B, and re-testing will be paid for by the Kansas Immunization Program.
- c. If HBsAg is present and anti-HBs is **NOT** detectable after receipt of three doses of hepatitis B vaccine, the child is considered to be infected. The child should be evaluated in six months to determine if he or she is a carrier of hepatitis B.
3. KDHE does not recommend routine post-vaccination testing of contacts for serological response.
 4. HBIG and hepatitis B vaccinations **DO NOT** interfere with routine childhood vaccinations.
 5. Breast feeding poses no risk of hepatitis B infection for infants who have begun prophylaxis.
 6. If the mother is identified as HBsAg positive >1 month after giving birth, the infant should be tested for HBsAg. If the results are negative, the infant should be given the hepatitis B series. If the results are positive, further evaluation from a physician is needed.

PERINATAL HEPATITIS B SURFACE ANTIGEN CASE REPORT

CASE NUMBER (FOR KDHE)	HAWK Number (If applicable)	DATE INITIATED (Mo/Da/Yr)
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CLIENT INFORMATION

Last Name	Maiden Name	First Name	Middle Initial
Street Address			
City	Zip Code	COUNTY	
Occupation	Age (years)	Date of Birth (Mo/Da/Yr)	
Race <input type="checkbox"/> African American <input type="checkbox"/> Asian/Pacific Islander _____ (Ethnicity) <input type="checkbox"/> Caucasian <input type="checkbox"/> Alaskan/American Indian <input type="checkbox"/> Other Hispanic Ethnicity Yes / No			

LABORATORY INFORMATION

	Pos.	Neg.	Not Tested	Test Date (Mo/Da/Yr)
Hepatitis B surface antigen (HBsAg)	_____	_____	_____	____/____/____
IgM Hepatitis B core (IgM anti-HBc)	_____	_____	_____	____/____/____

CLINICAL DATA FOR HEPATITIS B

(Mo/Da/Yr)		
Date of first symptom	____/____/____	Was patient jaundiced? Yes/ No
Date of diagnosis	____/____/____	Was patient hospitalized for hepatitis B? Yes/ No
If hospitalized for hepatitis B, then complete the following:		
Hospital	Phone (____)	
City	County	

DELIVERY INFORMATION

Expected Delivery Date (Mo/Da/Yr)	Expected Delivery Hospital
____/____/____	

Case's Name (Last, First)_____

CONTACTS INFORMATION

ID #	Contact Name (Last, First)	Relationship to Case	Date of Birth (Mo/Da/Yr)	Date Screened (Mo/Da/Yr)	Test Results		Hepatitis B Vaccine		
					HBsAg	Anti-HBc	1 (Mo/Da/Yr)	2 (Mo/Da/Yr)	3 (Mo/Da/Yr)
	1				+ / --	+ / --			
	2				+ / --	+ / --			
	3				+ / --	+ / --			
	4				+ / --	+ / --			
	5				+ / --	+ / --			
	6				+ / --	+ / --			
	7				+ / --	+ / --			
	8				+ / --	+ / --			

INFANT INFORMATION

Infant's Name (Last, First)	Date of Birth (Mo/Da/Yr)	HBIG (Mo/Da/Yr)	Hepatitis B Vaccine			Date Screened* (Mo/Da/Yr)	Test Results		Revaccinate **
			1 (Mo/Da/Yr)	2 (Mo/Da/Yr)	3 (Mo/Da/Yr)		HBsAg	Anti-HBs	
							+ / --	+ / --	+ / --
							+ / --	+ / --	+ / --

* The screening on the infant should be done 3-9 months after completion of the hepatitis B series.

** Revaccinate only if both HBsAg and Anti-HBs are negative.

Completed by	Phone ()	Agency
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Please send completed forms to: Epidemiology Services Section, 1000SW Jackson, Suite 210, Topeka, KS 66612-1290

Phone 785/296-2951

Fax 785/291-3775